



## ECTU Central Office SOP ECTU\_IT\_23: Additional Requirements

Version No:	2.0
Issue Date:	23 Aug 2024
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Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
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Tanya Tharakan QA Manager	QA Authorisation	23-Aug-2024	 <a href="#">Tanya Tharakan (Aug 23, 2024 15:15 GMT+1)</a>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	10 <sup>th</sup> June 2016	New document. For clarity. The process described in this SOP was originally incorporated in the System Change Management SOP. When that SOP was reviewed a decision was taken to split the "Feature Release" and "Additional Requirements" tasks into separate SOPs.
2.0	06 Sep 2024	Updated to new template version. Changes made throughout the SOP to reflect current procedures.

The user of this document is responsible for ensuring it is the current version.

## 1.0 PURPOSE

This SOP describes the process of logging an additional requirement.

## 2.0 SCOPE

This SOP applies to all the research support systems developed in-house by Edinburgh Clinical Trials Unit.

This SOP applies to any release after the initial release.

## 3.0 RESPONSIBILITIES

The software developer or designee is responsible for the tasks detailed in this SOP.

## 4.0 PROCEDURE

### Recording an additional requirement

This procedure describes the process of recording an additional requirement for an existing production system.

**4.1** An additional requirement is identified through communication with project stakeholders.

**4.2** A new additional requirement is added to the list of additional requirements for the project. The following details are recorded for each additional requirement in the IT004 Additional Requirements Template, which can be adapted according to the requirements of the trial.

**4.2.1** The additional requirement counter is incremented by 1 and used as the numeric identifier for this particular additional requirement. This identifier is used as part of the System Release documentation. (IT003 System Release Document)

**4.2.2** A description of the additional requirement.

**4.2.3** The name and project role of the person requesting the additional requirement.

**4.2.4** The date of the request.

**4.2.5** A decision on whether or not the request will be implemented. If it's not to be implemented a reason must be given.

**4.2.6** Name and role of the person implementing the requirement.

**4.3** Each time a feature is released then the additional requirements list is, signed and dated by the responsible member of the system development team. This is then filed along with the System Release document in the project's documentation folder.

## 5.0 RELEVANT DOCUMENTS AND REFERENCES

### [ECTU Website](#)

- ECTU Central Office SOP ECTU\_IT\_03: Feature Release

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- IT003 System Release Document Template
- IT004 Additional Requirements Template

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Final Audit Report

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